K003158

DEC 1 8 2000

510(k) Summary

Introduction	According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence
Submitter name, address, contact	Roche Diagnostics Corporation 9115 Hague Rd Indianapolis IN 46250 (317) 576-3544 Contact person: Kay A. Taylor Date prepared: October 6, 2000
Predicate device	The Roche CK-MB is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the Boehringer Mannheim [now doing business as Roche Diagnostics] CK-MB (K802521).
Device name	Proprietary name: Roche CK-MB Common name: CK-MB Classification name: U.V. Method, CPK Isoenzymes
Device description	Anti-CK-M antibodies in the reagent inhibit the CK-M subunit in the sample without affecting the CK-B subunits. The CK-B activity is determined by the CK NAC method and corresponds to half the CK-MB activity.

510(k) Summary, continued

Intended use

For the quantitative in vitro determination of the MB isoenzyme of creatine kinase in human serum and plasma on automated clinical chemistry analyzers.

Indications for use

The determination of CK-MB aids in the diagnosis of myocardial ischemia, e.g. in acute myocardial infarction or myocarditis.

Substantial equivalence

The Roche CK-MB assay is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to Boehringer Mannheim [now doing business as Roche Diagnostics (K802521).

Substantial equivalence-similarities

The following table compares the Roche CK-MB assay with the predicate device.

Feature	CK-MB	Predicate Device
Intended use	For the quantitative in vitro determination of the MB isoenzyme of creatine kinase in human serum and plasma on automated clinical chemistry analyzers.	For the quantitative determination of CK-MB isoenzyme activity in serum or plasma.
Sample type	Plasma and serum	Plasma and serum
Sample tubes	Heparin, EDTA	Heparin, EDTA
Wavelength	Primary – 340 nm Secondary – 546 nm	340 nm

Substantial equivalence - differences

The following table compares the Roche CK-MB assay with the predicate device.

Feature	CK-MB	Predicate Device
Assay protocol	UV assay with immunological inhibition of CK-M	Spectrophotometric assay with inhibition of CK-M
Key Material	Mouse anti-human CK-M monoclonal antibody	Goat anti-human CK-M antibody
Reagent format	• Liquid	• Granulate
Control (frequency)	• Precinorm CK-MB & CK-MB/LD-1 or other suitable control material • Control interval per institution requirements	• CK-MB Control Serum, in kit • Each run
Measuring range	5 – 2300 U/L at 37°C	Linear up to 170 U/L at 37°C

Substantial equivalence – performance characteristics

The performance characteristics of the Roche CK-MB assay and the predicate device are compared in the table below.

Feature	CK-MB	Predicate Device
With-in run precision (%CV)	4.3% @ 27.7 U/L 0.5% @ 127 U/L 0.6% @ 160 U/L	Precision: 3.1% @ 28 U/L 1.8% @ 70.2 U/L 2.4% @ 256.8 U/L
Between day precision (%CV)	3.3% @ 27.4 U/L 0.8% @ 126 U/L 0.7% @ 160 U/L	
Analytical sensitivity	5 U/L	1.7 U/L
Method Comparison	Roche CK-MB Liquid (y) and CK-MB Granulate (x) on Roche/Hitachi 917 $y = 0.86x - 0.75$ $r = 0.999$	Not available
Calibration frequency	• With each lot • As required by institution QC procedures	• Each run
Limitations	• No significant interference from conjugated bilirubin up to an I index of 60 or unconjugated bilirubin up to an I index of 20. • Hemolysis interferes. • No significant interference from lipemia up to an L index of 600. • Patients with a disposition to macro-CK formation, implausibly high CK-MB values may be measured in relation to the total CK.	• Sample free of hemolysis

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Ms. Kay A. Taylor
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DEC 1 8 2000

Re: K003158
Trade Name: Roche CK-MB
Regulatory Class: II
Product Code: JHW, JIX
Regulatory Class: I
Product Code: JJX
Dated: October 6, 2000
Received: October 10, 2000

Dear Ms. Taylor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): N/A K003158

Device Name: Roche CK-MB

Indications For Use:

Immunoinhibition assay for the quantitative in vitro determination of the MB isoenzyme of creatine kinase in human serum and plasma on automated clinical chemistry analyzers. The determination of CK-MB aids in the diagnosis of myocardial ischemia, e.g. in acute myocardial infarction or myocarditis.

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Carol C. Benson for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003158